UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,763	06/05/2006	Vincenzo De Leo	SER-105	2323

23557 7590 06/16/2009

SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
PO Box 142950
GAINESVILLE, FL 32614

EXAMINER	
BORGEEST, CHRISTINA M	
ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
06/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/565,763	DE LEO ET AL.	
	Examiner	Art Unit	
	Christina Borgeest	1649	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 June 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *12 and 14-29*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Bridget E Bunner/
Primary Examiner, Art Unit 1647

Continuation of 11. does NOT place the application in condition for allowance. To summarize the rejections of record, the rejection of claims 12, 14-27 and 29 under 35 U.S.C. 102(b) as being anticipated by Foresta et al. (Fertil Steril. 2002, 77: 238-244—of record) is maintained for reasons of record and the following. The rejection of claims 12, 14-17, 19-27 and 29 under 35 U.S.C. 102(b) as being anticipated by Acosta et al. (Fertil Steril. 1991; 55: 1150-6—of record) is maintained for reasons of record and the following. Finally, the rejection of claim 28 is under 35 U.S.C. 103(a) as being unpatentable over Acosta et al. (cited above—of record) and as applied to claims 12-17, 19-27 and 29 above and further in view of Bouloux et al. (Human Reprod. 2001, 16: 1592-1597) is maintained for reasons of record and the following. With regard to all of the rejections, Applicants argue "that inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency." (citation omitted by Examiner). Applicants further point out that extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference. Finally, Applicants point out with respect to both the rejections under 102(b) and 103(a) that the claims require the treatment of a male having gamete numerical chromosomal alterations, and neither Acosta et al. nor Foresta et al. provide any indication that such individuals were treated by the administration of FSH.

This argument has been fully considered but is not persuasive. First to reiterate, Foresta et al. teach the successful treatment of oligozoospermic males with normal basal FSH levels with recombinant FSH or rFSH (see p. 244, left column, last paragraph) at a dose of 100 IU on alternate days (see p. 243, right column, 2nd paragraph), thus meeting the claim limitations of claims 12-27 and 29, because in the context of this rejection, the phrase "at or about 150 IU/dose" is given its broadest reasonable interpretation, and 100 IU is "at or about 150 IU/dose." In addition, Acosta et al. teach treatment of infertile males with pure FSH at a dose of 150 IU three times a week for 3 months with the result that six healthy, full-term pregnancies were achieved (see abstract; p. 1151, right column, last full paragraph; p. 1154, right column, penultimate paragraph; p. 1155, right column, 4th paragraph). Furthermore, Acosta et al. teach that basal sperm concentration values in men with normal FSH levels was higher than those with elevated FSH levels, and that men with elevated FSH levels had low sperm counts, i.e., oligozoospermia (see p. 1154, left column, 2nd paragraph). Furthermore, Acosta et al. meet the exact limitations of the dose of FSH (between 75-300 IU/dose or 150 IU/dose) and frequency of administration (i.e., three times a week or every other day). Note that in this rejection, "at or about 150 IU/dose" is interpreted more narrowly. The Examiner's concerns with regard to patient population overlap remain. Foresta et al. teaches a patient population with oligozoospermia (for example, see p. 239, left column, under "Subjects"). Acosta et al. also teach a patient population with "severe quantitative and qualitative semen abnormalities" (see abstract). Both references teach success with respect to FSH treatment (outlined above). McInnes et al. was cited by the Examiner in these rejections as extrinsic evidence that males with oligozoospermia have a significantly increased rate of aneuploidy and diploidy. This reference provides evidence that patients with oligozoospermia, such as those reported in Foresta and Acosta are likely to have "gamete numerical chromosomal abnormalities." The evidence cited by the Examiner clearly indicates that the patient population reported in Foresta and Acosta significantly overlaps with patients having gamete chromosomal abnormalities, as required by the instant claims. Because this overlap is signficant, it represents more than just a possibility or a probability. Note also that the claims require only a method comprising adminstration of an effective amount of FSH to a male having a gamete numerical chromosomal alteration, and does not require that the population be identified as such by any further method step. The rejections are maintained because the same patient population is treated with the same agent at the same dose.